

§ 866.3940

identify *Vibrio cholerae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cholera caused by the bacterium *Vibrio cholerae* and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salts) depletion, and by vomiting, muscle cramps, and prostration. If untreated, the severe dehydration may lead to shock, renal failure, cardiovascular collapse, and death.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59227, Nov. 3, 1998]

§ 866.3940 West Nile virus serological reagents.

(a) *Identification.* West Nile virus serological reagents are devices that consist of antigens and antisera for the detection of anti-West Nile virus IgM antibodies, in human serum, from individuals who have signs and symptoms consistent with viral meningitis/encephalitis. The detection aids in the clinical laboratory diagnosis of viral meningitis/encephalitis caused by West Nile virus.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance entitled "Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus." See § 866.1(e) for the availability of this guidance document.

[68 FR 61745, Oct. 30, 2003]

§ 866.3950 In vitro human immunodeficiency virus (HIV) drug resistance genotype assay.

(a) *Identification.* The in vitro HIV drug resistance genotype assay is a device that consists of nucleic acid reagent primers and probes together with software for predicting drug resistance/susceptibility based on results obtained with these primers and probes. It is intended for use in detecting HIV genomic mutations that confer resistance to specific antiretroviral drugs, as

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an aid in monitoring and treating HIV infection.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled "Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay." See § 866.1(e) for the availability of this guidance document.

[72 FR 44382, Aug. 8, 2007]

§ 866.3980 Respiratory viral panel multiplex nucleic acid assay.

(a) *Identification.* A respiratory viral panel multiplex nucleic acid assay is a qualitative in vitro diagnostic device intended to simultaneously detect and identify multiple viral nucleic acids extracted from human respiratory specimens or viral culture. The detection and identification of a specific viral nucleic acid from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection when used in conjunction with other clinical and laboratory findings. The device is intended for detection and identification of a combination of the following viruses:

- (1) Influenza A and Influenza B;
- (2) Influenza A subtype H1 and Influenza A subtype H3;
- (3) Respiratory Syncytial Virus subtype A and Respiratory Syncytial Virus subtype B;
- (4) Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus;
- (5) Human Metapneumovirus;
- (6) Rhinovirus; and
- (7) Adenovirus.

(b) *Classification.* Class II (special controls). The special controls are:

(1) FDA's guidance document entitled "Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay;"

(2) For a device that detects and identifies Human Metapneumovirus, FDA's guidance document entitled "Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays;" and

(3) For a device that detects and differentiates Influenza A subtype H1 and subtype H3, FDA's guidance document entitled "Class II Special Controls